REMARKS

Claims 1-50 are pending in the application. Claims 23-50 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention. Claims 1-22 have been rejected.

Claims 1 and 17 have been amended. Support for the amendments can be found throughout the specification and the claims as originally filed. No new matter has been added by the proposed amendments. Amendment of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to more particularly point out and distinctly claim the invention to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

Claim Rejection Under 35 U.S.C. § 112 Second Paragraph

Claims 1-22 are rejected under 35 U.S.C. § 112 Second Paragraph as failing to point out and distinctly claim the subject matter that Applicants regard as the invention. In particular, the Office Action asserts that the abbreviated term 'KIAA' has not been explained either in the specification or in the claims.

In response, Applicants have amended claims 1 and 17, and dependent claims thereto, to specifically recite KIAA 18 and KIAA 96, two proteins that are fully described in the specification (*See*, for example, Specification page 3, lines 1-18, and lines 21-22). These amendments render this rejection moot. Accordingly, the Examiner is respectfully requested to withdraw the rejection.

Claim Rejection Under 35 U.S.C. § 102

Claims 1-17 are rejected under 35 U.S.C. § 102(b) as being anticipated by An *et al.* (U.S. 5,972,615). In particular, the Office Action asserts that:

> "An et al. teaches a method of assessing whether a subject is afflicted with prostate cancer....[using a marker] selected from the group consisting of one or more KIAA markers (tranglutaminase in this case) (Column 6, lines 1-10 and TABLE 4)."

The office action further states, with regard to Claim 17, that:

> "KIAA markers (in the absence of specific definition in the specification or claims) are broadly interpreted as comprising transglutaminase, cytokeratin 15, and/or semenogelin II composition..."

Applicants respectfully disagree with the basis for this rejection. However, in order to expedite prosecution of the application, Applicants have amended independent claims 1 and 17, and dependent claims thereof, to specifically recite two KIAA markers, "KIAA 18 and KIAA 96." The Examiner is respectfully requested to withdraw the anticipatory rejection in light of the claim amendments and following remarks.

The An *et al.* reference does not teach or suggest the use or even the existence of any "KIAA" markers, let alone the specific proteins, KIAA 18 and KIAA 96, that are recited in the amended claims. The An *et al.* reference teaches using "prostate-specific transglutaminase," one member of the transglutaminase superfamily. The sequence of the "prostate-specific transglutaminase" described in An *et al.* "matches GenBank Accession #s L34840, I20492" (See Col. 73, lines 28-29 and TABLE 4 of An *et al.*). An *et al.* teaches using only *modest variations* of those sequences as markers for prostate cancer to account for normal human variation (See Col. 74, lines 26-39). In contrast, Applicants claim KIAA 18 and KIAA 96, proteins with completely different sequences (GenBank Accession Nos. D13643 and D43636, respectively) (See Specification page 82, line 19) than those described in An *et al.* An *et al.* do not teach or suggest using KIAA 18 and/or KIAA 96 as markers for prostate cancer. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Claim Rejection Under 35 U.S.C. § 103

Claims 18-22 are rejected under 35 U.S.C. § 103 as being obvious over An *et al.* (U.S. 5,972,615) in view of Lal *et al.* (U.S. 6,096,308). In particular, the Office Action asserts that:

> An et al. teaches the method of claims 1-17 as described above including the transglutaminase (which is considered as KIAA 18) expression in prostate cancer.
>
> An et al. does not teach KIAA 96 expression (which is disclosed in the specification page 3, lines 12-13 as a serine-threonine kinase) in prostate cancer.
>
> Lal et al. teaches KIAA 96 expression (which is considered as serine-threonine kinase) in prostate cancer (Column 1, line 57 to Column 2, line 17).
>
> It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the KIAA 96 expression (which is considered as a serine-threonine kinase) in prostate cancer of Lal et al. in the method of An et al....

Applicants respectfully traverse the rejection. Claim 18, and dependent claims thereof, require the detection of "KIAA 18 and KIAA 96, or a combination thereof." While An *et al.* teaches that the specific transglutaminase, "prostate-specific transglutaminase" with GenBank Accession Nos. L34840, I20492" (See Col. 73, lines 28-29 and TABLE 4 of An *et al.*) and derivations thereof, can be used in diagnosing prostate cancer, An *et al.* do not teach or even suggest using other members of the transglutaminase superfamily or KIAA 18. As discussed above, An *et al.* fails to teach or suggest using KIAA 18. Furthermore, as acknowledged by the Examiner, "An et al. does not teach KIAA 96 expression." Therefore, An *et al.* does not teach either of the two markers recited in claims 18-22 of Applicants application.

The deficiencies of An *et al.* are not remedied by Lal *et al.* The Examiner asserts that "[a]n ordinary practitioner would have been motivated to substitute and combine the KIAA 96 expression (which is considered as serine-threonine kinase) in prostate cancer of Lal et al. in the method of An et al." since "PKC is a synonym for a family of serine/threonine kinases that has been associated with signal transduction...[and] the regulation of cell death as well (Column 1, line 67 to Column 2, line 4". While Lal *et al.* teach using a purified protein kinase (PK) in the treatment of cancer, Lal *et al.* do not teach or suggest using KIAA 96 as a marker for monitoring prostate cancer. The Background section of Lal *et al.* states that "An example of a PKC which is

involved in the growth-inhibitory action of transforming growth factor-betal (TGF-betal) in PC3, a human prostate cancer cell line, is protein kinase K02B 12 from *C. elegans*." Lal *et al.* does not teach that *human* serine/threonine kinases can be used as *markers* for prostate cancer in humans. In fact, the sequences of PK described in Lal *et al.* for the treatment of cancer are not even members of the PKC family of kinases. Therefore, based on the teachings in Lal *et al.* one skilled in the art would not be motivated to test the hundreds of known serine threonine kinases for use as markers for prostate cancer. Therefore, Lal. *et al.* does not teach that either KIAA 96 or KIAA 18 is a marker for prostate cancer.

For all the reasons recited above, it is clear that neither the An *et al.* reference nor the Lal *et al.* reference discloses or suggests the methods of the present invention, that there is no motivation to combine these references, and that even if combined they do not disclose or suggest the method of the present invention. Thus, these references fail to disclose or suggest every element recited by independent claim 18. Because every limitation of an independent claim is imported to dependent claims, claims 19-22 are also allowable. Applicants, therefore, respectfully request that the Examiner withdraw all rejections.

CONCLUSION

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the amendments and remarks are not deemed to overcome the grounds for rejection, the Examiner is kindly requested to telephone the undersigned representative to discuss any remaining issues.

Respectfully submitted,

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